K070267 (pg 1 of 3)

3. 510(K) SUMMARY

Applicant / Sponsor:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy Friddle Team Leader, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	Sigma High Performance Unity Knee Resurfacing System
Common Name:	Compartmental Knee Prosthesis System
Classification Name:	21 CFR 888.3530: Knee joint femorotibial, metal/polymer semi-constrained cement prosthesis, Class II
Product Codes:	HRY, NPJ
Substantially Equivalent Devices:	DePuy GCK (K061648) DePuy Preservation Unicondylar Knee (K040268) DePuy Sigma Unicompartmental Knee, submitted as the J&J PFC Unicondylar Knee System (K910968)

AUG 17 2007

Device Description:

The Sigma High Performance Unity Knee Resurfacing System is composed of unicompartmental femoral components, patellofemoral trochlear components, unicompartmental tibial components and patellar components. These components may be used in various combinations to create: a single unicompartmental femorotibial replacement for either the medial or lateral side of the knee; two unicompartmental femorotibial replacements for both the medial and lateral sides of the knee; a patellofemoral replacement; a bicompartmental patellofemorotibial replacement for the medial or lateral side of the knee; or a tricompartmental patellofemorotibial replacement for the medial and lateral sides of the knee.

This submission adds metal-backed unicompartmental tibial components to the previously cleared GCK System. The Sigma High Performance Unity Knee Resurfacing System metal-backed unicompartmental tibial components consist of wrought forged Co-Cr-Mo unicompartmental tibial trays and XLK cross-linked UHMWPE unicompartmental tibial inserts. The trays and inserts are available in 6 sizes and in left medial / right lateral and right medial / left lateral configurations. Each tibial insert is available in 5 thicknesses. The Sigma High Performance Unity Knee Resurfacing System metal-backed unicompartmental tibial components are intended for use with the previously cleared GCK unicompartmental femoral components.

Intended Use:

The Sigma High Performance Unity Knee Resurfacing System is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for Use:

The Sigma High Performance Unity Knee Resurfacing System is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All Sigma High Performance Unity Knee Resurfacing System components are intended for CEMENTED USE ONLY.

Summary of Technologies/Substantial Equivalence:

The Sigma High Performance Unity Knee Resurfacing System metal-backed unicompartmental tibial components have the same indications and intended use, a similar design and the same articulating geometry as the previously cleared GCK all polyethylene unicompartmental tibial components. The manufacturing materials are identical to materials that have been previously cleared in other DePuy knee prostheses.

Non-Clinical Testing:

Engineering analysis, wear simulator testing and mechanical testing were performed to demonstrate the substantial equivalence of the Sigma High Performance Unity Knee Resurfacing System metal-backed unicompartmental tibial components to the predicate devices.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the subject Sigma High Performance Unity Knee Resurfacing System Tibial Components and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Nancy Friddle
Team Leader, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

AUG 17 2007

Re: K070267
Trade/Device Name: Sigma High Performance Unity Knee Resurfacing System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY, NPJ
Dated: May 23, 2007
Received: May 25, 2007

Dear Ms. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K070267

Device Name: Sigma High Performance Unity Knee Resurfacing System

Indications for Use:

The Sigma High Performance Unity Knee Resurfacing System is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All Sigma High Performance Unity Knee Resurfacing System components are intended for CEMENTED USE ONLY.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruch M.D. for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070267